



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/642,650	08/19/2003	John Brown Thomsen	010085-027	3735

21839 7590 06/30/2004

BURNS DOANE SWECKER & MATHIS L L P
POST OFFICE BOX 1404
ALEXANDRIA, VA 22313-1404

EXAMINER

KIM, VICKIE Y

ART UNIT	PAPER NUMBER
----------	--------------

1614

DATE MAILED: 06/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/642,650

Applicant(s)

THOMSEN ET AL

Examiner

Vickie Kim

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 37 and 38 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 37 and 38 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☒ Certified copies of the priority documents have been received in Application No. 09/416940.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 8/19/03.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: ____.

DETAILED ACTION

Priority

1. This application appears to be a division of Application No. 10/012,303, filed 12/12/2001. Acknowledgment is made of applicant's claim for all the domestic priority under 35 U.S.C. 120 and foreign priority under 35 U.S.C. 119(a)-(d).

Status of Application

1. Acknowledgement is made of preliminary amendment(2nd) filed 09/26/2003 . Upon entering the amendment, the claims 9-36 are canceled. The claims 1-8, 37-38 are pending and presented for the examination.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Scope of Enablement

1. Claims 1-8 and 37-38 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims because the specification, while being enabling for treating specific skin disorders such itching(pruritus) or swelling cause by an insect bite, does not reasonably provide enablement for treating all possible skin disorders(claims 37-

Art Unit: 1614

38) or skin disorders caused by insect bite(claims 1-8) by using the composition as claimed.

Attention is directed to *In re Wands*, 8 USPQ 1400 (CAFC 1988) at 1404 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls) at 547 the court recited eight factors:

1) The nature of the invention:

The invention provides related to a treatment of all the skin disorders, optionally caused by insect bite.

2) The state of the prior art:

The art does not recognizes or teach that no examples exist for efficacy of a single product against all types of claimed conditions or disease generally. The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation.

3) The relative skill of those in the art:

The relative skill of the those in the art is high.

4) The predictability of the art:

The state of the prior art recognizes that the treatment of skin diseases or conditions remains highly unpredictable.

5) The breadth of the claims:

The claims are very broad.

6) The amount of direction or guidance provided:

The specification only disclosed itching or swelling treatment that is caused by insect bite(see pages 45-47).

Therefore, the specification has enabled for itching or swelling treatment which is caused by insect bite or sting. The specification provides no direction and no guidance for treating other skin disorders (e.g. skin infections, pain, hair loss) due to insect bite or sting.

7) The presence of absence of working example:

As stated above, the specification only exemplifies mosquito, bee or wasp bite or sting and itching or swelling treatment cause by said animals. There is no working example using the claimed composition for other skin disorders(e.g. skin infections, pain, hair loss) due to insect bite or sting(see claims 1-8); or other skin disorders(skin cancers , wrinkles, hyperpigmentation, etc) not necessarily related to insect bites or sting(see claims 37-38).

8) The quality of experimentation necessary:

The true fact of the state of the art in the treatment of skin diseases is expressed well, "The significance of particular treatment of skin diseases for modifying different aspects of biological activity and pathological process cannot be predicted a priori but must be determined from the case to case by painstaking experimental study and when the above factors are weighed

Art Unit: 1614

together, one of ordinary skill in the art would be burdened with undue "painstaking experimentation study " to determine the efficacy against all the skin disorders, or skin disorders related to insect bite or sting.

Claim Objections

1. Claims 1-8 are objected to because of the following informalities: In claim 1, line 8, a phrase "the sting or bite is cured" is awkward. It is noted that the symptoms or conditions caused by sting or bite is subject to be treated, but not the bite or sting itself. Since the meaning of the claims are understandable, the claims in question are objected for the reasons above. However, appropriate correction is required to clarify and describe the invention precisely, as to enable any person skilled in the art to use the same by the inventor of carrying out his invention.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim Rejections - 35 USC § 102/103

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-8 are rejected under 35 U.S.C. 102(b) as being anticipated by, or in alternatively, obvious over Blackman et al(US 5013545).

Blackman et al(US'545, hereafter) teach an aqueous gel composition comprising ethanol(about 60-90%) as an active agent, water(about 0.5-30%) and gelling agent(about 0.5-5%) for treating skin conditions caused by insect bite, see abstract and column 4, lines 50-54.

As to the claims 4-8, US'545 also teaches an aqueous gel composition comprising ethanol(about 60-90%) as an active agent, water(about 0.5-30%) and gelling agent(about 0.5-5%) for treating skin conditions can be used alone or concomitantly with an added topical active pharmaceutical agent to improve activity, see column 5, line 45-57.

As to the limitations recited in the preamble(i.e. the time period retained in the skin, for example, 1 minute- 48 hours, 5 minutes- 6 hours) are inherently met because the composition taught by the cited reference(US'545) and the instant claims is substantially same and thus, one would have envisaged substantially same therapeutic efficacy including the time retained in the skin after topical

Art Unit: 1614

application. Otherwise, it would have been obvious that the gelled composition must be retained in the skin enough time so that the time allows the drug be absorbed thru the skin layer by preventing quick evaporation as recognized and evidenced by the disclosure of US'545 patent(see background of the patented invention, column 1) and this obvious, absent evidence to the contrary.

It is noted that the limitation(i.e. more than 90) is embraced by the term "about 90%") because "about" encompasses the range "+% and -%, around 90%" . For instance, the term'about" is often refers to the range "+/- 10%" and it is well accepted in the art. Therefore, the patent teaches the claimed subject matter, or obvious that the reasonable expectation of success can be observe by the patented composition in comparison with the claimed invention, absent evidence to the contrary.

Thus, all the critical elements required by the claims are taught by the cited reference.

5. Claims 1-4 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by or in alternatively, obvious over Frost(US4,923,875).

The claims read on a method of treating skin disorders caused by insect bite or sting by applying a composition comprising more than 90% by weight alkanol selected from C₁₋₄ alkane monools, diols and triols and less than 10% by weight water.

Frost(US'875, hereafter) teaches a method of treating dermatological disorders caused insect bite, comprising administering a composition comprising more than 90% alcohol and gelling agent, see examples 4 and 7, and column 2,

Art Unit: 1614

lines 45-47. For instance, in examples 4 and 7, the composition comprising alcohols(88.5gm SDA40alcohol +5gm propylene glycol(=propaine diol)) and 3g hydroxypropyl cellulose(gelling agent) for treating pruritus(itching) and irritations.

As mentioned above, the time period retained in the skin are inherently met because the composition taught by the cited reference(US'875) and the instant claims is substantially same and thus, one would have envisaged substantially same therapeutic efficacy including the time retained in the skin after topical application. Otherwise, it would have been obvious, absent evidence to the contrary.

As to the claims 37-38, the mixture of different alkanols (C1-4) in which the ratio of propanol to ethanol is in the range of 10:1 or 1:10 would have been obvious when the teaching of Frost is learned carefully. As mentioned above, examples 4 and 7 utilizes the mixtures of different alcohols. One would have been motivated to make such mixture because titrating the ration is considered to be minor variation and easily determined within the level of the skilled artisan to optimize the therapeutic effecticity. The techniques and skills are easily available and they are also commonly practiced in the art(see PTO892).

Thus, all the critical elements required by the claims are taught by the cited reference.

6. Claims 37-38 are rejected under 35 U.S.C. 102(b) as being anticipated by, or in alternatively, obvious over Marks (US4247547).

Claim 37 is drawn to a method of treating skin disorders using a mixture of different alkanols (C3 and C2) in which the ratio of propanol to ethanol is in the

Art Unit: 1614

range of 10:1 to 1:10. Claim 38 is drawn to a method of treating skin disorders using a mixture of different alkanols (C1,3 and/or 4 + C2) in which the ratio of C1,3 and/or 4 alcohol to ethanol is in the range of 10:1 to 1:10.

Marks teaches a topical gel comprising a mixture(50/50) of ethanol+isopropanol; ethanol+propylene glycol; or propylene glycol(=propane diol)+isopropanol for treating dermatological diseases(e.g. acne), wherein ethanol used is 95% by volume ethyl alcohol, see examples 8-13 and column 2, lines 57. The patented composition exemplified contains more than 95% of alcohol content. It further contain gelling agent as well, see column 2, lines 65-68 and examples 8-13. Thus, one would have envisaged 0.1-about 4% of water content. Otherwise, it would have been obvious to one of ordinary skill in the art to expect the small amount of water(0.1-10%) existed in the composition because alcohol is known to be a hygroscopic compound and tends to absorb the water from the moisture into the composition, and thus obvious, absent evidence to the contrary.

Thus, the claimed subject matter is well taught and not patentably distinct over the prior art of the record.

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

Art Unit: 1614

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).


8. Claims 1-8 and 37-38 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 13-15 of U.S. Patent No. 5,981,605. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter of US'605 (patent) drawn to a method of treating infected skin by topical application of gel composition comprising more than 90% C1-4 alkanol or the mixture thereof as an active agent. All the critical elements required by the instant claims are taught by the patented claims. Since alcohols (e.g. rubbing alcohols) have been known for long time as antiitching or antiseptic against insect bite or sting, one would have been easily modified US'605 teaching to incorporate the method for treating skin disorders caused by insect bite or sting to get maximum benefit because alcohols are easily accessible. In addition to that, conveniences and low manufacturing cost would maximize user's benefits and thus, such modification could be carried out with reasonable expectation of success and with great demand. The scope of the instant claims are embraced by the patented claims and are not considered to be patentably distinct over the patented claims.

Thus, all the claims are properly included in this rejection.

Conclusion

9. No claim is allowed.
10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 571-272-0579. The examiner can normally be reached on Tuesday-Friday.
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Chris Low be reached on 571-272-0953. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



VICKIE KIM
PRIMARY EXAMINER

Vickie Kim
June 28, 2004
Art unit 1614